

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/948,124	10/09/97	REINHERZ	E DFCI-522A

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EXAMINER

BANSAL, G

ART UNIT

PAPER NUMBER

1642
24

DATE MAILED: 03/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	08/948,124	Applicant(s)	Reinhen et al
Examiner	Gleeta Bansal	Group Art Unit	1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

Responsive to communication(s) filed on 12/22/00

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

Claim(s) 41, 45, 63(?), 64-71 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 41, 45, 64-71 [need clarification on 63] is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892

Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948

Other _____

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DETAILED ACTION

1. Applicant's remarks filed December 22, 2000 (Paper No: 23/D) is acknowledged. Accordingly, claims 41 and 45 have been amended, 53-62 have been cancelled and 64-73 have been added. It is not clear if Applicant intended to cancel claim 63 or not. In the body of the arguments Applicant states that 53-63 have been cancelled, but have not instructed it to be done in the amendment. Clarification is requested. Claims 41, 45, 64-71 are being examined.

Response to Arguments

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 41, 45, and new claims 64-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear in claims 41 and 45 if the "an isolated caspase or procaspase" is the same caspase or procaspase as that in immature thymocytes. It is also not clear from the claims as recited how a method of identifying an agent which enhances the activity of a caspase or procaspase expressed in immature thymocytes (preamble) is connected to steps (a) and (b) in claim 41 or to the conclusion in claim 45. Is Applicant claiming a new caspase or procaspase in immature thymocytes that is different from the one taught by Fearnhead?

4. Rejection of claims 41, 45 and new claims 64-71 under 35 U.S.C. 103(a) is maintained for reasons set forth in the previous office action. Applicant's arguments have been reviewed and noted, but they are not persuasive. Applicant argues that Fearnhead et al do not teach a method of enhancing procaspase or caspase activity, or the desirability of identifying agents which do so. Applicant argues that the thrust of Fearnhead et al work was aimed at understanding the stages of apoptosis and that they concluded that apoptosis in thymocytes was regulated by different

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proteases. Applicant also states that Fearnhead et al concluded that apoptosis induced by different stimuli was inhibited/potentiated by TLCK and Z-VAD. Applicant continues to argue that Fearnhead et al do not teach or suggest compounds used in their studies affect an isolated caspase or procaspase. It is submitted that Fearnhead teaches the concept that enhancing caspase activity by agents such as dexamethasone etc. was also directly tied to enhancement of apoptosis in immature thymocytes. Applicant fails to recognize that Fearnhead et al teaching clearly suggest that apoptosis in immature thymocytes was associated with caspase/procaspase activity. Such conclusion was based on the use of known agents that affect caspase/procaspase activity. Though Fearnhead may not teach contacting isolated caspase with an agent and assess its enhancing effect on caspases, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to extend these studies to look for agents that enhance the activity of isolated caspase/procaspase.

5. No claims are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

7. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308- 4995.

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 7, 2001


GEETHA P. BANSAL
PRIMARY EXAMINER